

REMARKS

Claims 1-16 are pending in this application. Claims 17, 20-22 and 26 are canceled herein without prejudice to pursuit of their prosecution in a continuation application. Claims 18 and 19 are amended herein for clarity to more particularly define the invention. Support for these amendments is found in the language of the original claims and throughout the specification, as set forth below. Applicants assert that no new matter is added by these amendments and their entry and consideration are respectfully requested. In light of these amendments and the following remarks, applicants respectfully request consideration of this application and allowance of the pending claims.

I. Recordation of Interview Summary in accordance with M.P.E.P. § 713.04

Applicants wish to make of record the Interview Summary prepared and submitted to applicants by Examiner Sitton on December 20, 2006. Applicants concur that this Interview Summary accurately reflects the substance of the personal interview on December 18, 2006 in which Examiner Sitton, Supervisory Examiner Shukla, applicants' representative, Dr. Mary Miller, and inventor, Dr. Redford Williams, participated. Applicants appreciate the opportunity to discuss this application and pending claims with the Examiners.

II. Priority

The Office Action states that the pending claims have not been awarded the filing date of U.S. provisional application no. 60/162, 390 (the '390 application), filed October 29, 1999, from which the present application claims priority.

Applicants respectfully point out that the claims herein are indeed entitled to the filing date of October 29, 1999 of the '390 application because the '390 application does indeed disclose the claimed subject matter and also demonstrates an association between cardiovascular diseases and other diseases in response to psychological stress and the long allele of the serotonin transporter gene promoter.

In particular, as discussed and highlighted during the December 18, 2006 interview, the specification of the '390 application as filed provides support for claim 18 as presented herein at least on page 1, lines 28-30; page 2, lines 20-25; page 3, lines 10-11; page 4, line 13 through page 5, line 7, and in the Abstract. Furthermore, support for claim 19 as presented herein as well as dependent claims 23-25 can be found in the '390 application at least on page 1, lines 20-22; page 1, line 29 through page 2, line 5; page 3, lines 15-31; page 4, lines 27-28; page 5, lines 5-7 and in the Abstract.

In response to the Examiner's comment in the Interview Summary that the second paragraph of the "Summary of the Invention" appears to conflict with the claim language, as applicants explained during the December 18, 2006 interview, the invention is and always has been the association of the serotonin transporter gene promoter long allele with increased risk of disease (e.g., cardiovascular disease) in response to psychological stress. Thus, the reference to short alleles in the second paragraph of the Summary of the Invention section of the '390 application was an inadvertent typographical error that was made in the provisional application and subsequently corrected in the nonprovisional application filed October 27, 2000 and the applicant apologizes for any confusion resulting from this error. Evidence is present in the '390 application that the applicant was in possession of the invention as presented in the currently pending claims, as set forth above and in particular in Example 1, wherein the identified association between the long allele genotype and increased cardiovascular reactivity to psychological stress is described, with no mention of any such association with a short allele genotype.

As also discussed during the December 18, 2006 interview, included herewith is a Declaration under 37 C.F.R. § 1.132 of inventor, Dr. Redford Williams, describing various publications that demonstrate that an association between cardiovascular disease and an increased physiological response to psychological stress, which physiological response is increased blood pressure, was known in the art at the time of the present invention.

Furthermore, the '390 application describes a list of diseases that can result from psychological stress, including cardiovascular disease (page 3, lines 15-25) and also provides data showing an association between the long allele genotype of the serotonin transporter gene promoter and an increased physiological response to psychological stress, which physiological response is increased blood pressure (pages 4 and 5). These teachings in the '390 application of the association between the long allele genotype and an increased physiological response to psychological stress (e.g., "cardiovascular reactivity" as described on page 5 of the '390 application), along with the knowledge in the art of the association between cardiovascular reactivity and cardiovascular disease demonstrate sufficient enabling support for the invention as claimed herein in the '390 application as filed. Thus, the subject matter of the claimed invention is supported in the disclosure of the '390 application and is thus entitled to the October 29, 1999 filing date and applicants respectfully request that the Examiner acknowledge on the record the priority status demonstrated by applicants.

III. Rejection under 35 U.S.C. § 102(b)

A. The Office Action states that claims 17-19 and 24 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Arinami et al.

As set forth above, applicants submit that the claimed subject matter is entitled to the filing date of October 29, 1999 of the '390 application from which the present application claims priority. On that basis, the Arinami et al. publication, which is dated June, 1999, is allegedly only a prior art reference, if at all, under 35 U.S.C. § 102(a).

As discussed during the December 18, 2006 interview, the claims as presented herein are distinguished from Arinami et al., which provides no teaching or suggestion of identifying a human subject having an increased likelihood of having an increased physiological response to psychological stress or an increased risk of developing a cardiovascular disease in response to an increased physiological response to psychological stress, wherein said physiological response is increased blood pressure,

comprising detecting the presence of at least one serotonin transporter gene promoter long allele in the subject, whereby the presence of at least one serotonin transporter gene promoter long allele identifies the subject as having an increased likelihood of having an increased physiological response to psychological stress. Therefore, Arinami et al. does not anticipate the pending claims.

Applicants further assert that the Arinami et al. publication is not available as a prior art reference for rejecting claims of the present invention, on the basis that the applicant conceived of and reduced to practice the claimed invention prior to the publication date of the Arinami et al. reference. Specifically, the applicant provides herein a copy of a Declaration under 37 CFR § 1.131 submitted previously in response to the November 7, 2005 Office Action whereby the inventor, Dr. Redford Williams, declares that the conception and reduction to practice of the claimed invention was prior to June, 1999, thereby rendering the Arinami et al. reference unavailable as prior art to the present invention. Thus, this rejection has been rendered moot and the applicant respectfully requests its withdrawal.

B. The Office Action states that claims 17, 18, 20 and 21 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Hanna et al.

As discussed during the December 18, 2006 interview, the claims as presented herein are distinguished from Hanna et al., which provides no teaching or suggestion of identifying a human subject having an increased likelihood of having an increased physiological response to psychological stress or an increased risk of developing a cardiovascular disease in response to an increased physiological response to psychological stress, wherein said physiological response is increased blood pressure, comprising detecting the presence of at least one serotonin transporter gene promoter long allele in the subject, whereby the presence of at least one serotonin transporter gene promoter long allele identifies the subject as having an increased likelihood of having an increased physiological response to psychological stress. Therefore, Hanna et al. does

not anticipate the pending claims and withdrawal of this rejection is respectfully requested.

IV. Rejection under 35. U.S.C. § 112, first paragraph (enablement)

The Office Action states that claims 17-26 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

As discussed during the December 18, 2006 interview, the claims as presented herein recite a method of identifying a human subject having an increased likelihood of having an increased physiological response to psychological stress, wherein the physiological response is increased blood pressure and having an increased likelihood of developing a cardiovascular disease in response to an increased physiological response to psychological stress, wherein the physiological response is increased blood pressure, comprising detecting the presence of at least one serotonin transporter gene promoter long allele in the subject. Dependent claims further recite that the cardiovascular disease can be hypertension, coronary heart disease or stroke. Support for these claims is found throughout the '390 provisional application, as described above, as well as in the specification of the non-provisional application, U.S. Application No. 09/698,870, filed October 27, 2000, at least, for example, on page 1, line 30; page 2, lines 1-11; Figures 4 and 5; page 4, lines 29-30; page 5, line 1; page 5, lines 25-29; page 8, lines 3-5; page 9, lines 3-7; page 10, lines 4-7 and 12-16; and the Abstract.

The Examples section of both the '390 and '879 applications provide the results of several studies that were carried out to demonstrate that the presence of at least one serotonin transporter gene promoter long allele is associated with an increased physiological response to psychological stress that is increased blood pressure (cardiovascular reactivity). In the enclosed Declaration and as discussed during the interview, Dr. Williams describes the data in his 2003 publication and explains that the long allele genotype remained significantly associated with an increased physiological response that is increased blood pressure among different genders and ethnic groups.

Additionally, as discussed at the December 18, 2006 interview, other scientific groups have published papers that substantiate the presently claimed invention. As described in the attached Declaration, two publications (Cato et al. and Fumeron et al.) describe studies wherein the long allele genotype was found to be directly correlated with cardiovascular disease, thereby further demonstrating that one of skill in the art could practice the claimed invention without undue experimentation.

Thus, the claimed invention is clearly enabled in the specification as filed, on the basis that the specifications of both the provisional '390 application and the pending non-provisional application adequately demonstrate that the present invention links the following two associations in humans, that of 1) an increased physiological response to psychological stress, wherein the physiological response is increased blood pressure (cardiovascular reactivity) and the presence of at least one serotonin transporter gene promoter long allele; and 2) an increased physiological response to stress (cardiovascular reactivity) and the incidence of cardiovascular disease, the latter of which was known in the art at the time of the present invention, as set forth in the enclosed Declaration by Dr. Williams.

For at least these reasons, it would be readily apparent to one of ordinary skill in the art that the present invention establishes an association between the presence of at least one serotonin transporter gene promoter long allele and an increased likelihood of developing cardiovascular disease. Hence, undue experimentation would not be required to identify this association and carry out the methods of this invention. For these reasons, the applicant asserts that the present invention is adequately enabled and respectfully requests the withdrawal of this rejection and the allowance of the pending claims.

V. Rejection under 35 U.S.C. § 112, first paragraph (written description)

The Office Action states that claims 19 and 22-26 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate written description for the phrase "cardiovascular disease associated with an increased physiological response to stress."

Claim 19 as presented herein recites "cardiovascular disease in response to an increased physiological response to psychological stress," which is adequately described in the '390 provisional application at least in originally filed claim 3 and in the Abstract and in the '870 non-provisional application at least in originally filed claim 1 and in the Abstract. Thus, as discussed during the December 18, 2006 interview, claim 19 as presented herein and those claims dependent therefrom are adequately described in the present application pursuant to the requirements for written description and the applicant respectfully requests withdrawal of this rejection.

In view of the foregoing amendments and remarks, the applicant respectfully requests that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In the event that the Examiner fails to find allowable subject matter upon review of the claims and remarks as presented herein, the applicant respectfully requests a telephone interview with the Examiner prior to the issuance of any further actions for this application.

A check in the amount of \$905.00 (\$510.00 as fee for a three month extension of time and \$395.00 as fee for a Request for Continued Examination) is enclosed. This amount is believed to be correct. However, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



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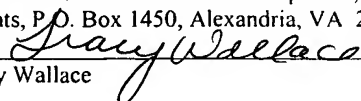
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Tracy Wallace